IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

UNITED STATES OF AMERICA,
ex rel. BROOK JACKSON,

Plaintiff,

v. **Case No. 1:21-CV-00008-MJT**

VENTAVIA RESEARCH GROUP, LLC,
et al.,

Defendants.

UNITED STATES' MOTION TO INTERVENE
AND TO DISMISS PURSUANT TO 31 U.S.C. § 3730(c)(2)(A)

The United States moves to intervene and dismiss pursuant to 31 U.S.C. § 3730(c)(2)(A) of the False Claims Act (FCA). The United States has good cause to intervene and is entitled to dismissal of the FCA claims in Relator's Second Amended Complaint under *United States ex rel. Polansky v. Executive Health Resources, Inc.*, 599 U.S. 419 (2023), and the applicable standard of Fed. R. Civ. P. 41(a)(1).

BACKGROUND

I. FCA Overview

The FCA, 31 U.S.C. §§ 3729-3733, imposes civil penalties and treble damages on any person or entity that (1) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," in violation of 31 U.S.C. § 3729(a)(1)(A), and (2) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," in violation of § 3729(a)(1)(B). Civil suits to enforce the FCA may be brought either by the Attorney General, *id.* § 3730(a), or by a private person who files suit "for the person and for the United States Government" in the name of the United States, *id.* § 3730(b)(1). The private person is known as a "relator" and the suit is called a *qui tam* action. *Id.*

After a period for investigation, the FCA requires the United States to notify the court whether it will intervene in the *qui tam* action or decline to take over the action. 31 U.S.C. § 3730(b)(4). Where the United States intervenes, the Government assumes "the primary responsibility for prosecuting the action" and is not bound by any act of the relator. *Id.* § 3730(c)(1). As the party with primary responsibility over the action, the United States may proceed with the action, settle the case over the relator's objection, *id.* § 3730(c)(2)(B), or dismiss the case over the

relator's objection, *id.* § 3730(c)(2)(A). If the United States declines to intervene, "the person bringing the action shall have the right to conduct the action." *Id.* § 3730(b)(4). But even after declining to intervene, the United States may still intervene "upon a showing of good cause," 31 U.S.C. § 3730(3), in which case it then assumes primary responsibility for the action and assumes all of the same rights described above.

II. Relator's *Qui Tam* Allegations

Relator Brook Jackson filed her *qui tam* action on January 8, 2021, against Pfizer, Inc.; Icon PLC; and her former employer, Ventavia Research Group, LLC. Dkt. 2. Relator Jackson alleged that defendants violated the protocol for the Pfizer-BioNTech COVID-19 vaccine clinical trial at three study sites in Texas and that defendant Pfizer misrepresented the safety and efficacy of the Pfizer-BioNTech COVID-19 vaccine to the Food and Drug Administration (FDA). *Id.*

The United States declined to intervene on January 18, 2022. Dkt. 13. On February 22, 2022, Relator Jackson filed an amended complaint that was substantially similar to the original complaint. Dkt. 17. Motion to dismiss briefing concluded on September 20, 2022. Dkt. 37, 50-51, 53. The United States filed a Statement of Interest Supporting Dismissal of the Amended Complaint on October 4, 2022. Dkt. 70.

The Court granted defendants' motions to dismiss on March 31, 2023. Dkt. 96. On April 28, 2023, Relator Jackson filed a Rule 59(e) Motion to Amend the Court's Order of Dismissal and permit her leave to file a second amended complaint asserting an alternative theory that Pfizer knowingly submitted false or fraudulent data to FDA, thereby fraudulently inducing the agency's issuance of Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 vaccine and improperly rendering it eligible for subsequent payment by the Government. Dkt. 97. The Court granted Relator Jackson leave to file a second amended complaint on August 9, 2023. Dkt. 108. She filed her Second Amended Complaint on October 5, 2023. Dkt. 118. The Second Amended Complaint alleges that Pfizer fraudulently induced the FDA's issuance of EUA by failing to disclose clinical trial protocol violations, submitting false data to FDA, and failing to disclose the existence of effective alternative treatments for COVID-19. *Id.* Relator Jackson also alleges a series of flaws in the design, conduct, and analysis of the Pfizer-BioNTech COVID-19 vaccine clinical trial. *Id.* Defendants moved to dismiss the Second Amended Complaint on October 20, 2023. Dkt. 119, 120, 121. Relator Jackson filed her Opposition to Defendants' Motions to Dismiss on December 19, 2023. Dkt. 127. Defendants filed their Replies in support of their motions to dismiss on January 19, 2024. Dkt. 129, 130, 132.

ARGUMENT

I. The United States Has Good Cause To Intervene for the Purpose of Dismissal

The Supreme Court held in *Polansky* that if the United States wishes to dismiss a *qui tam* suit pursuant to § 3730(c)(2)(A), it must first intervene and become a party. *Polansky*, 599 U.S. at 430-31. The FCA provides that the United States may intervene in a *qui tam* suit after declining upon a showing of "good cause." 31 U.S.C. § 3730(c)(3). In its decision that the Supreme Court affirmed "across the board," the Third Circuit explained that "showing 'good cause' is neither a burdensome nor unfamiliar obligation," but instead "a uniquely flexible and capacious concept, meaning simply a legally sufficient reason." *United States ex rel. Polansky v. Executive Health Resources, Inc.,* 17 F.4th 376, 387 (3d Cir. 2021), *aff'd* 599 U.S. 419 (2023).

This flexible standard for evaluating "good cause" applies even at a later stage in a *qui tam* litigation. *Polansky*, 17 F.4th at 381-82 (noting that "the parties and the District Court invested considerable time and resources in the case."). In ultimately upholding dismissal in *Polansky*, the Supreme Court recognized that "the Government's interest in the suit is the same [at any stage] – and is the predominant one." *Polansky,* 599 U.S. at 434. *Qui tam* suits are "brought in the name of the Government" and "the injury they assert is exclusively to the Government." *Id.* at 424–25 (citing § 3730(b)(1)).

In this case, the United States has good cause to intervene because it seeks to dismiss Relator Jackson's Second Amended Complaint. As the Third Circuit concluded in *Polansky*, the Government's request to dismiss the suit "itself establishes good cause to intervene." *Polansky,* 599 U.S. at 429 n.2; *see Brutus Trading, LLC v. Standard Chartered Bank*, No. 20-2578, 2023 WL 5344973, at *2 (2d Cir. Aug. 21, 2023) (government's (c)(2)(A) motion amounted to a motion to intervene as well); *United States ex rel. Carver v. Physicians Pain Specialists of Alabama, P.C.*, 2023 WL 4853328, at *6 n.4 (11th Cir. July 31, 2023) (ruling that "the same grounds that support dismissal also provide good cause to intervene").

II. Legal Standard for the United States' Motion to Dismiss Relator's FCA Claims

Once the United States intervenes in a *qui tam* action, the FCA authorizes it to dismiss such an action, even if the relator objects: "The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion." 31 U.S.C. § 3730(c)(2)(A).

The Supreme Court's recent decision in *Polansky* held that district courts should apply the standard of Rule 41(a) when evaluating a motion to dismiss under § 3730(c)(2)(A). 599 U.S. at 424. ("We … hold that in handling such a motion, district courts should apply the rule generally governing voluntary dismissal of suits:

Federal Rule of Civil Procedure 41(a)"). If the United States moves to dismiss before the defendants have served an answer or a motion for summary judgment, as the United States is doing here, then dismissal may be accomplished merely by the filing of a "notice of dismissal." Fed.R.Civ.P. 41(a)(1). The district court "has no adjudicatory role" other than to dismiss the action, except where dismissal may implicate constitutional constraints. *Polansky*, 599 U.S. at 436 n.4. Indeed, even in cases where the defendant has already filed an answer and the United States seeks dismissal under Rule 41(a)(2), a motion to dismiss under § 3730(c)(2)(A) "will satisfy Rule 41 in all but the most exceptional cases."[1] *Id.* at 437.

Here, the Government investigated and evaluated the claims alleged by the Relator in her original and amended complaints. While a defendant's fraud in inducing FDA to authorize or approve a product may be the basis for a viable FCA claim, here, FDA was aware of Relator's allegations of clinical trial protocol violations that she witnessed at Ventavia prior to the initial EUA. Further, FDA has

[1] Even where the defendant has already answered or moved for summary judgment, the standard remains quite deferential to the government's determination that that dismissal is warranted. Dismissal in such cases is governed by Rule 41(a)(2), and it is warranted "on terms that the court considers proper." The Supreme Court indicated that that standard would be met so long as the United States provides good grounds for thinking that [the] suit would not do what all *qui tam* actions are supposed to do: vindicate the Government's interests. "Absent some extraordinary circumstances, that sort of showing is all that is needed for the Government to prevail on a [section 3730(c)(2)(A)] motion to dismiss." *Polansky*, 599 U.S. at 438.

had continued access—as the information has become available—to the Pfizer COVID-19 vaccine clinical trial protocol and results, reported adverse event data, and scientific research that Relator identifies to support her fraudulent inducement claim. As recently as January 5, 2024, FDA Commissioner Robert Califf, MD and Director of FDA's Center for Biologics Evaluation and Research, Peter Marks, MD, Ph.D., published an editorial in the Journal of the American Medical Association reiterating the importance of vaccination, including vaccination to protect against COVID-19.[2] They noted, "contrary to a wealth of misinformation available on social media and the internet, data from various studies indicate that since the beginning of the COVID-19 pandemic tens of millions of lives were saved by vaccination."[3] The anticipated discovery and litigation obligations associated with the continued litigation of this case will impose a significant burden on FDA, HHS, and DOJ. The United States should not be required to expend resources on a case that is inconsistent with its public health policy.

III. No In-Person Hearing is Necessary

An in-person hearing is not required and would not aid the Court in adjudicating the Government's motion to dismiss. *Polansky* did not specify what procedures would satisfy the requirement of a hearing but did not require a hearing

[2] Marks P, Califf R. Is Vaccination Approaching a Dangerous Tipping Point? JAMA. Published online January 05, 2024. doi:10.1001/jama.2023.27685.
[3] *Id.*

in all matters. In evaluating how a district court should reconcile a relator's right to a hearing with the fact that the district court has no adjudicatory role under Rule 41(a)(1), the Supreme Court suggested that a hearing might establish a constitutional floor, inquiring into any credible allegations that dismissal might "violate the relator's rights to due process or equal protection," but did not elaborate on what would constitute such a violation. *Polansky*, 599 U.S. at 436 n.4. Those types of constitutional concerns clearly are not present in this case. Accordingly, no hearing is required in this matter. *Id.; see Brutus Trading, LLC*, 2023 WL 5344973, at *3 (holding that no in-person hearing was required, explaining that "the district court met the hearing requirement by carefully considering the parties' written submissions"); *U.S. ex. rel. Guglielmo v. Leidos, Inc., et al.*, No. 19-1576, D.D.C. Feb. 20, 2024) (granting the United States' motion to dismiss under Fed. R. Civ. P. 41(a)(1) without an in-person hearing).

CONCLUSION

For the foregoing reasons, the United States respectfully requests that, finding the United States had good cause to intervene, the case be dismissed pursuant to 31 U.S.C. § 3730(c)(2)(A).

Date: March 12, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was served electronically via CM/ECF to all parties, on this 12th day of March, 2024.

/s/ Erin Colleran
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